Citation:

Wang YF, Yancy WS Jr, Yu D, Champagne C, Appel LJ, Lin PH. The relationship between dietary protein intake and blood pressure: Results from the PREMIER study. *J Hum Hypertens*. 2008 Nov; 22 (11): 745-754.

PubMed ID: 18580887

Study Design:

Prospective cohort

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the association of dietary protein intake with blood pressure and particularly, the independent relationship of animal and plant protein with blood pressure.

Inclusion Criteria:

Individuals who were not taking anti-hypertensive medications and had a systolic blood pressure (SBP) of 120 to 159mmHg and/or diastolic blood pressure (DBP) of 80 to 95mmHg.

Exclusion Criteria:

Participants without at least one diet recall at each assessment time period.

Description of Study Protocol:

Recruitment

The present study is a secondary analysis using data from the PREMIER trial, an 18-month, multi-center, three-group randomized trial designed to determine the effect of two multi-component lifestyle interventions on blood pressure for individuals who met criteria for a six to 12-month trial of non-pharmacological therapy. Those who met criteria were individuals who were not taking anti-hypertensive medications and had a SBP of 120 to 159mmHg or a DBP of 80 to 95mmHg.

Design

Prospective cohort.

Dietary Intake/Dietary Assessment Methodology

24-hour dietary recall (unannounced): Two recalls (one weekday and one weekend day) were obtained by phone interview.

Blinding Used

- Staff members involved in follow-up data collection were blinded to treatment assignment
- Intervention staff members were blinded to all outcome data during the entire study.

Intervention

Two multi-component 18-month interventions (14 group sessions and four individual sessions during the first six months and then monthly group sessions for the last 12 months) and a control group:

- *Intervention one:* A behavioral lifestyle intervention designed to help patients follow long-established recommendations on blood pressure control (losing weight if overweight, reducing sodium intake, increasing physical activity and limiting alcohol intake
- *Intervention two:* A behavioral lifestyle intervention combining the established recommendations plus the DASH (Dietary Approaches to Stop Hypertension) eating plan, which included the goals of increasing intake of fruits, vegetables and low-fat dairy products, and reducing intakes of saturated fat and total fats
- *Control group (advice only):* 30-minute advice session after randomization and again after the six-month data collection.

Statistical Analysis

- For analysis in this report, the three treatment groups were combined to allow better estimation of and more efficient inferences on parameters of interest (but treatment group indicators were always included in the model as independent variables)
- Multivariable linear regression was performed both cross-sectionally at all the three time-points and longitudinally from baseline to six and 18 months, respectively
- Longitudinal analyses were also performed by examining the association between the changes of blood pressure and changes of dietary protein intakes between baseline and six months and baseline and 18 months
- Logistic regression was performed to examine the association of hypertension status with various nutrient and food intake variables at each time-point separately.

Data Collection Summary:

Timing of Measurements

Dietary intake and blood pressure were assessed at baseline, six and 18 months.

Dependent Variables

- Hypertension (SBP ≥140mmHg or DBP ≥90mmHg)
- SBP (mmHg)
- DBP (mmHg).

Independent Variables

- Total protein intake
- Animal protein intake

- Plant protein intake.

Control Variables

- Age
- Gender
- Race
- Treatment group
- Study
- Site
- Education
- Income
- Baseline blood pressure
- Alcohol intake
- Physical activity
- Waist circumference
- Urinary creatinine and sodium and nutrients that might be related to blood pressure control (intake ofprotein, fat, fiber, calcium and potassium).

Description of Actual Data Sample:

- *Initial N:* 810
- *Attrition (final N):* 810
- *Age:* Mean of 50.5 years (range, 25 - 79 years)
- *Ethnicity*: 64.2% non-Hispanic White, 34.4 African-American, 1.4% other
- *Other relevant demographics:*
  - 91% had a college education
  - 87% were non-smokers
- *Anthropometrics:*
  - Mean (SD) body mass index of 33.1 (5.8)kg/m^2
  - 37.5% with hypertension
- *Location:* Four US clinical centers.

Summary of Results:

Key Findings

- For the cross-sectional analyses, there was no association between baseline total protein intake and baseline blood pressure (all P>0.05), nor between 18-month total protein intake and 18-month blood pressure
- After adjusting for covariates, plant protein was strongly inversely associated with both SBP (P=0.0045) and DBP (P=0.0096) at six months (but not 18 months)
- After adjusting for covariates, fruit and vegetable intake was strongly inversely associated with both SBP (P=0.0003) and DBP (P=0.0157) at six months (but not 18 months)
- Change in plant protein intake from baseline to six months was inversely associated with change in SBP (P=0.0486), but not with change in DBP(P=0.0759) (and there were no significant associations at 18 months)
- In multivariate logistic regression analyses, plant protein intake was significantly inversely associates with the risk of hypertension at six months, without adjusting for dietary fiber

intake (OR=0.75, 95% CI: 0.60 to 0.95)
- Fruit and vegetable intake was significantly inversely associated with risk of hypertension (OR=0.85, 95% CI: 0.77 to 0.95) in multivariate analyses.

Author Conclusion:

Plant protein had a beneficial effect on blood pressure and was associated with a lower risk of hypertension at six months, but no association was found between total or animal protein and hypertension.

Reviewer Comments:

Study Strengths

- *Large sample size*
- *In-clinic blood pressure measurements*
- *Adjustment for many potential confounders, cross-sectional and longitudinal analyses.*

Study Limitations

- *The 24-hour dietary recalls may not have represented usual dietary intake*
- *The true association between blood pressure and protein intake over the study period may have been minimized, because the total plant protein intake was only 4.9% of total calories at baseline and increased by very little over the study with small variation.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes